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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,168	12/11/2001	Stephen R. Gorfine	010692-004531US	3329
20350	7590	01/29/2003		
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER	
			TATE, CHRISTOPHER ROBIN	
			ART UNIT	PAPER NUMBER
			1654	
			DATE MAILED: 01/29/2003	
			5	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/021,168	Applicant(s) Gorfine
	Examiner Christopher Tate	Art Unit 1654



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Dec 12, 2001 and Apr 16, 2002
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.
- 4) Claim(s) 37-51 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims 37-51 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 37-45, drawn to a kit comprising multiple unit dosages of a semisolid composition consisting essentially of a NO donor (nitroglycerin) within a specified range to treat an anal disease, classified in class 435, subclass 810, for example.
- II. Claims 46-49, drawn to an analgesic composition comprising nitroglycerin, sucralfate with and without lidocaine, classified in class 514, subclass 742, for example.
- III. Claims 50-51, drawn to a method of treating painful conditions of an anal region via applying nitroglycerin, sucralfate with and without lidocaine, classified in class 514, subclass 882, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-II (distinct products) and III (method) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

In the instant case, there are numerous ways to treat painful conditions of an anal region (e.g.,

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hemorrhoids) including using various well known over-the-counter topical medicines. In addition, the distinct products of Groups I-II can be used, e.g., to treat heart ailments.

The products of Groups I and II are distinct, each from the other, because the product of Group I requires that it be in kit form within a container which comprises multiple unit dosages of a pharmaceutical carrier in conjunction with nitroglycerin within specified dosage ranges, whereas the product of Group II does not. Conversely, the product of Group II requires a combination of nitroglycerin, sucralfate, with and without lidocaine, whereas the product of Group I does not.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are distinct for the reasons given above and the search required for each Group is not required for other Groups, restriction for examination purposes as indicated is proper.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.



Christopher R. Tate
Primary Examiner, Group 1654